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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,619	04/15/2004	Johannes J. Platteeuw	SYN-0044	6264

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EXAMINER	
TRAN, SUSAN T	
ART UNIT	**PAPER NUMBER**
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/824,619	PLATTEEUW ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-35 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 11/01/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-20 and 22-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimizu et al. US 6,328,994, in view of Sherwood et al. US 5,585,115.

Shimizu teaches an orally disintegrable tablet comprising 25-40% fine granule of active material, 3-50% crystalline cellulose, 3-50% low-substituted hydroxypropyl cellulose, and other excipients (disintegrant) (column 5, lines 10-13; column 10, lines 13-39; and column 11, lines 34-42). Active material includes omeprazole, and is coated with an enteric polymer (column 5, lines 14-24). Crystalline cellulose includes microcrystalline cellulose (MCC) (column 10, lines 13-24). Shimizu also teaches the tablet exhibits hardness of about 1-20 kg, and an oral disintegration time of about 30 second or less (column 12, lines 42-51).

Shimizu does not teach the use of the claimed microcrystalline cellulose.

Sherwood teaches an excipient suitable for pharmaceutical tablet formulation comprising (MCC) having average particle size from about 10 μm to about 1000 μm, and from about 0.1% to about 20% silicon dioxide content (abstract; column 5, lines 1-44; and column 11, lines 1-18). Sherwood further teaches the use of up to 70% of the

MCC as an excipient in a tablet dosage form (examples 10-12). Thus, it would have been obvious to one of ordinary skill in the art to modify the oral dosage form of Shimizu using the MCC in view of the teaching of Sherwood to obtain the claimed invention, because Sherwood teaches an MCC that improved compressibility, because Sherwood teaches an MCC that possesses excellent disintegration and dissolution properties, and because Shimizu teaches the desirability of obtaining a direct compressed tablet that is useful for orally disintegrable administration.

Claims 1-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Betzing et al. US 5,776,492, in view of Sherwood et al. US 5,585,115 and Shimizu et al. US 6,328,994.

Betzing teaches a rapidly disintegrating binder-free tablet comprising microcrystalline cellulose and tramadol in a ratio of at 2:1 (abstract). Examples 1-5 showed the use of about 70% MCC, tablet hardness of 60-80N, and disintegration time of 30-55 seconds. Betzing further teaches the use of other additives (examples).

Betzing does not teach the use of the claimed microcrystalline cellulose.

Sherwood teaches an excipient suitable for pharmaceutical tablet formulation comprising (MCC) having average particle size from about 10 μm to about 1000 μm, and from about 0.1% to about 20% silicon dioxide content (abstract; column 5, lines 1-44; and column 11, lines 1-18). Sherwood further teaches the use of up to 70% of the MCC as an excipient in a tablet dosage form (examples 10-12). Thus, it would have been obvious to one of ordinary skill in the art to modify the oral dosage form of Betzing

using the MCC in view of the teaching of Sherwood to obtain the claimed invention, because Sherwood teaches an MCC that improved compressibility, because Sherwood teaches an MCC that possesses excellent disintegration and dissolution properties, and because Betzing teaches the desirability of obtaining a rapidly disintegrable tablet having tablet hardness and disintegrating time suitable for pharmaceutical use.

Betzing further does not explicitly teach the tablet is orally disintegrable.

Shimizu teaches an orally disintegrable tablet comprising 25-40% fine granule of active material, 3-50% MCC, 3-50% low-substituted hydroxypropyl cellulose, and other excipients (disintegrant) (column 5, lines 10-13; column 10, lines 13-39; and column 11, lines 34-42). Shimizu further teaches an oral disintegration time of about 30 second or less (column 12, lines 42-51). Thus, it would have been obvious to one of ordinary skill in the art to prepare an orally disintegrable tablet in view of the teaching of Shimizu, because Shimizu teaches an orally disintegrable tablet that can easily be administered without the need of water, which can be used for treatment of various diseases to the aged or children (abstract).

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lehtola et al., and Raghunathan are cited as of interest for the teachings of dosage forms comprising silicified MCC.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit 1615